

REMARKS**Amendments to the Claims**

Claims 1, 4, 5 and 11 have been amended.

Claims 3 and 16 have been canceled.

Claims 1, 4, 5 and 11 have been amended to recite "ATCC Accession No. PTA-7045."

Support for these amendments is found in the specification, as amended, for example, at page 25, lines 16-23. In addition, support for reference to the cell line for the A2 antibody is found in the priority application US Serial No. 07/670,827, filed March 18, 1991, at page 19, lines 14-20.

Claims 1, 4, 5 and 11 have been amended to recite "antigen-binding fragment." Support is found in the specification, for example, at page 9, lines 8-11; page 17, lines 2-8. In addition, support is found in the specification of priority application US Serial No. 07/670,827, filed March 18, 1991, for example, at page 1, lines 5-12 and page 11, lines 10-20.

Claims 1, 4, 5 and 11 have been further amended to recite that the antibody or antigen-binding fragment "binds to a neutralizing epitope of human TNF α *in vivo* with an affinity of at least 1×10^8 liter/mole, measured as an association constant (K_a), as determined by Scatchard analysis." Support is found in the specification, for example, at page 21, lines 16-23; page 60, line 25 to page 61, line 5; and Example X, particularly at page 80, line 24 to page 81, line 12. In addition, support is found in the specification or priority application US Serial No. 07/670,827, filed March 18, 1991, for example, at page 13, lines 5-8; page 18, lines 17-19; page 20, lines 3-6; and Example X, particularly, at page 67, line 12 to page 68, line 25.

Claims 1, 4 and 11 have been further amended to recite "human constant region." Claim 5 has been amended to recite IgG1 "human" constant region. Support is found in the specification, for example, at page 10, lines 8-15; page 17, lines 2-8; page 31, line 6 to page 32, line 2; and page 34, lines 16-21. In addition, support is found in the specification of priority application US Serial No. 07/670,827, filed March 18, 1991, for example, at page 9, lines 21-23; page 12, lines 18-26, page 26, lines 6-19; and page 52, lines 18-20.

Claims 1, 4, 5 and 11 have been further amended to recite that the administrated antibody "competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) to human TNF α ." Support is found in the specification, for example, at page 19, line 17 to page 20, line 2 and page

30, lines 5-12. In addition, support is found in the specification of priority application US Serial No. 07/670,827, filed March 18, 1991, for example, at page 12, line 24 to page 13, line 4; page 14, lines 3-9; and page 19, lines 3-10.

No new matter has been added by the amendments. Therefore, entry of the amendments into the application is respectfully requested.

Amendments to the Specification

Applicants have amended the specification at page 25, lines 16-23 to recite ATCC Accession No. "PTA-7045", and to recite that c134A was deposited pursuant to the Budapest Treaty requirements with the American Type Culture Collection (ATCC), "10801 University Boulevard, Manassas, Virginia 20110-2209, on September 22, 2005."

Support for the amendments and the deposit of the cell line for the A2 antibody is found in the specification, for example, at page 25, lines 16-23. In addition, support is found in the priority application US Serial No. 07/670,827, filed March 18, 1991, at page 19, lines 14-20.

No new matter has been added by the amendments. Therefore, entry of the amendments into the application is respectfully requested.

Priority

The Examiner states that "[n]either the priority applications nor the instant application [] provides a sufficient description of the subgenus '[TNF α -mediated] cachexia associated with cancer', as currently claimed." (emphasis omitted) Further, the Examiner states that "the issue of priority [] and new matter [] is concerned with the written description of the diseases or conditions targeted in the claimed methods." However, the Examiner acknowledges that "the mechanism of treatment via TNF- α -specific antibodies would be the same or nearly the same...regardless of the particular TNF- α -mediated disease or condition."

For the reasons of record, Applicants maintain that Claims 1-2, 4-11, 14-15 and 17-20 are entitled to claim the benefit priority application USSN 07/670,827 (filed March 18, 1991) and that USSN 07/670,827 provides sufficient written description for Applicants' claimed methods of treating cachexia associated with cancer.

Rejection to Claims 1-11 and 14-20 Under 35 U.S.C. § 112, first paragraph

Claims 1-11 and 14-20 have been rejected 35 U.S.C. § 112, first paragraph, as the disclosure does not reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. The Examiner states that “[t]he specification as originally filed does not provide support for the invention as now claimed: ‘TNF α -mediated cachexia associated with cancer’ or ‘via the lungs’ (claim 16).”

While Applicants disagree with the Examiner’s position and reserve their rights to file continuing or divisional applications to pursue these claims, in order to further prosecution, Applicants have canceled Claim 16, thereby obviating the rejection to this claim.

In regard to Claims 1-11, 14-15 and 17-20, Applicants maintain, for the reasons of record, and for the reasons described above, that they were in possession of the claimed invention as the time the application was originally filed.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection to Claims 1, 3-5, 11 and 14-20 Under 35 U.S.C. § 112, first paragraph

Claims 1, 3-5, 11 and 14-20 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner states that the cA2 antibody must be known and readily available to the public, or obtainable by a repeatable method set for in the specification, or else a deposit of the cell line/hybridoma may be made in order to satisfy the enablement requirement.

37 C.F.R. § 1.809 (b)(1) states that “[t]he applicant for patent or patent owner shall reply to the rejection under paragraph (a) of this section by (1) In the case of an applicant for patent, either making an acceptable original...deposit, or assuring the Office in writing that an acceptable deposit will be made....” In addition, 37 C.F.R. § 1.809 (d) states that “[f]or each deposit made pursuant to these regulations, the specification shall contain: (1) The accession number for the deposit; (2) The date of deposit; (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and (4) The name and address of the depository.”

While Applicants disagree with the Examiner's position and reserve their rights to file continuing or divisional applications to pursue these claims, in order to expedite prosecution, and in accordance with 37 C.F.R. § 1.809 (b)(1), on September 22, 2005, Applicants deposited the cell line for the A2 antibody (designation c134A) with American Type Culture collection (ATCC) under the Budapest Treaty. The ATCC accession number is PTA-7045.

The specification at page 25, lines 16-23 has been amended to recite "As examples of antibodies according to the present invention, murine mAb A2 (ATCC Accession No. PTA-7045) of the present invention is produced by a cell line designated c134A." The specification at page 25, lines 16-23 has been further amended to recite "c134A was deposited pursuant to the Budapest Treaty requirements with the American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209, on September 22, 2005."

Further, Claims 3 and 16 has been canceled, Claims 1, 4, 5 and 11 have been amended to delete reference to cA2 and to recite "ATCC Accession No. PTA-7045" for the cell line of the A2 antibody. Dependent Claims 14-20 depend from these claims and, therefore, contain the same limitation. Applicants reserve their rights to file continuing or divisional applications to pursue these claims.

Support for the amendments and the deposit of the cell line for the A2 antibody is found in the specification, for example, at page 25, lines 16-23. In addition, support is found in the priority application US Serial No. 07/670,827, filed March 18, 1991, at page 19, lines 14-20.

Filed concurrently herewith is a Statement Under 37 C.F.R. §1.804, §1.806 and §1.808. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection to Claims 1, 3-5, 11 and 14-20 Under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 1, 3-5, 11 and 14-20 as indefinite in the recitation of "cA2". Specifically, the Examiner states that "the use of 'cA2' antibody as the sole means of identifying the claimed antibody renders the claim indefinite because 'cA2' is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation [] to define completely distinct hybridomas / cell lines." (emphasis omitted)

While Applicants disagree with the Examiner's position and reserve their rights to file continuing or divisional applications to pursue these claims, in order to further prosecution, as

discussed above, Claims 3 and 16 have been canceled and Claims 1, 4, 5 and 11 have been amended to delete reference to cA2 and to recite "ATCC Accession No. PTA-7045" for the cell line of the A2 antibody. As discussed above, on September 22, 2005, Applicants deposited the cell line for the A2 antibody with ATCC under the Budapest Treaty. The specification at page 25, lines 16-23 have been amended to recite the ATCC accession number, the date of deposit, a description of the biological material and the name and address of the depository.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection to Claims 1-11, 14-15 and 17-20 Under 35 U.S.C. § 102(b)

The Examiner has rejected Claims 1-11, 14-15 and 17-20 under 35 U.S.C. § 102(b) as being anticipated by *Le et al.* (WO 92/16553).

For the reasons of record, Applicants maintain that *Le et al.* (WO 92/16553) is not prior art. As discussed above, Applicants maintain that Claims 1-2, 4-11, 14-15 and 17-20 are entitled to claim the benefit priority application USSN 07/670,827 (filed March 18, 1991), which is prior to the date of publication of *Le et al.* (WO 92/16553). Reconsideration and withdrawal of the objection are respectfully requested.

Rejection to Claims 1 and 16 Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 1 and 16 under 35 U.S.C. § 103(a) as being unpatentable over *Le et al.* (WO 92/16553).

As discussed above, Applicants have canceled Claim 16. In regard to Claim 1, as discussed above, Applicants maintain that Claim 1 is entitled to claim the benefit priority application USSN 07/670,827 (filed March 18, 1991). *Le et al.* (WO 92/16553) is not prior art under 35 U.S.C. § 102 (b), as discussed above. Further, this reference is not prior art under 35 U.S.C. § 102 (a) or § 102 (e) because the application is not "by another."

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-11 and 14-20 Under the Judicially Created Doctrine of Obviousness-type Double Patenting

The Examiner has rejected Claims 1-11 and 14-20 under the judicially created doctrine of obviousness-type double patenting over Claims 1-16 of copending U.S. Serial No. 10/957,134 and Claims 1-70 of copending US. Serial No. 10/957,549. Applicants note this rejection and will file a terminal disclaimer upon indication that the only remaining rejections are the Double Patenting rejections.

Rejection of Claims 1-11 and 14-20 Under the Judicially Created Doctrine of Obviousness-type Double Patenting

The Examiner has rejected Claims 1-11 and 14-20 under the judicially created doctrine of obviousness-type double patenting over Claims 1-11 of U.S. Patent No. 5,919,452.

Applicants note this rejection and will file a terminal disclaimer upon indication that the only remaining rejections are the Double Patenting rejections.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Scott Siegel
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Filed: January 10, 2002 Examiner: Phillip Gambel
Confirmation No.: 3288

For: METHODS FOR TREATING CACHEXIA WITH CHIMERIC ANTI-TNF
ANTIBODIES

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Typed or printed name of person signing certificate LINDA M. BYRNES

STATEMENT UNDER 37 C.F.R. §1.804, §1.806 AND §1.808

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Pursuant to 37 C.F.R. §1.804, §1.806 and §1.808, the undersigned states as follows:

1. Murine mAb A2 (c134A) was deposited on September 22, 2005, and assigned ATCC Accession Number PTA-7045. The above-referenced application specifically identifies this biological deposit, which was deposited under the Budapest Treaty at the American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209. I am a person in position to corroborate that the biological material which was deposited is a biological material

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specifically identified in the priority application U.S. Serial No. 07/670,827, filed March 18, 1991 (the filing date of which is relied upon) as filed.

2. Deposit PTA-7045 will be maintained in a public depository for the enforceable life of the patent which issues from the above-referenced application, a term of at least thirty years from the date of deposit or at least five years after the most recent request for the furnishing of a sample of the deposit is received by the depository, whichever is longer.
3. In accordance with 37 C.F.R. §1.808(a)(1), access to deposit PTA-7045 will be available during the pendency of the above-referenced application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. §1.14 and 35 U.S.C. §122.
4. In accordance with 37 C.F.R. §1.808(a)(2), and except as permitted by 37 C.F.R. §1.808(b), all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent on the above-referenced application.

Respectfully submitted,

By 
G. Kevin Townsend

Dated: 12/20/05